Notice of Allowability	Application No.	o. Applicant(s)	
	09/721,391	VILE ET AL.	
	Examiner	Art Unit	
	Quang Nguyen, Ph.D.	1636	
The MAILING DATE of this communication appear All claims being allowable, PROSECUTION ON THE MERITS IS herewith (or previously mailed), a Notice of Allowance (PTOL-85) NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIOF of the Office or upon petition by the applicant. See 37 CFR 1.313	(OR REMAINS) CLOSED in a or other appropriate commural IGHTS. This application is su	this application. If not included nication will be mailed in due co	ourse. <b>THIS</b>
1. This communication is responsive to <u>8/9/04</u> .		•	
2. The allowed claim(s) is/are <u>9,35,37-43 and 46-49</u> .			
3. $\boxtimes$ The drawings filed on <u>22 November 2000</u> are accepted by	the Examiner.		
<ul> <li>4. ☐ Acknowledgment is made of a claim for foreign priority una) ☐ All b) ☐ Some* c) ☐ None of the: <ol> <li>1. ☐ Certified copies of the priority documents have</li> <li>2. ☐ Certified copies of the priority documents have</li> <li>3. ☐ Copies of the certified copies of the priority documents have International Bureau (PCT Rule 17.2(a)).</li> </ol> </li> <li>* Certified copies not received:</li> </ul>	been received. been received in Application	No	n from the
Applicant has THREE MONTHS FROM THE "MAILING DATE" noted below. Failure to timely comply will result in ABANDONM THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.	of this communication to file a ENT of this application.	a reply complying with the requi	irements
5. A SUBSTITUTE OATH OR DECLARATION must be submit INFORMAL PATENT APPLICATION (PTO-152) which give	itted. Note the attached EXAMes reason(s) why the oath or o	MINER'S AMENDMENT or NO declaration is deficient.	TICE OF
<ol> <li>CORRECTED DRAWINGS ( as "replacement sheets") musical including changes required by the Notice of Draftspers         <ul> <li>(a) including changes required by the Notice of Draftspers</li> <li>(b) including changes required by the attached Examiner's Paper No./Mail Date</li> </ul> </li> <li>Identifying indicia such as the application number (see 37 CFR 1. each sheet. Replacement sheet(s) should be labeled as such in the properties of the properties of</li></ol>	on's Patent Drawing Review of S Amendment / Comment or in 84(c)) should be written on the the header according to 37 CFR	n the Office action of e drawings in the front (not the ba 1.121(d).	
<ol> <li>DEPOSIT OF and/or INFORMATION about the depose attached Examiner's comment regarding REQUIREMENT I</li> </ol>	sit of BIOLOGICAL MATER FOR THE DEPOSIT OF BIOL	RIAL must be submitted. Not OGICAL MATERIAL.	te the
Attachment(s)  1. ☐ Notice of References Cited (PTO-892)  2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)  3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/0: Paper No./Mail Date  4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material	6. ⊠ Interview Sun Paper No./M 8), 7. ⊠ Examiner's A	lail Date mendment/Comment tatement of Reasons for Allowa	

## **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with attorney J. Patrick Finn III, Ph.D., on 9/1/04.

The application has been amended as follows:

In the claims:

Claim 9. (Currently amended) A composition comprising <u>a</u> nucleic acid, wherein said nucleic acid comprises:

- (a) a cell type-specific promoter for activating the expression of a gene in a specific cell type, wherein the cell type-specific promoter is human Tyr300 (SEQ ID. NO. 1);
- (b) a therapeutic gene sequence operably linked to said cell type-specific promoter;
- (c) an amplification promoter element for amplifying transcription of said therapeutic gene in said specific cell type, wherein said amplification promoter element is a heat shock element (HSE); and
- (d) a sequence encoding a transcription activator, said transcription activator for activating said amplification promoter element, and wherein said transcription activator is heat shock factor-1 (HSF-1).

Art Unit: 1636

Claim 35. (Currently amended) The composition of claim 9, wherein said sequence encoding said transcription activator sequence and said therapeutic gene sequence are on different nucleic acid molecules.

Claim 47. (Currently amended) The composition of claim 9, wherein said therapeutic gene sequence and the sequence encoding said transcription activator are both operably linked to said cell type-specific promoter.

Claim 48. (Currently amended) The composition of claim 9, wherein said therapeutic gene sequence and the sequence encoding said transcription activator are both operably linked to said amplification promoter element.

Claim 49. (Currently amended) The composition of claim 9, wherein said transcription activator is HSF-1 comprising a deletion of which lacks amino acid residues 202-316.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Quang Nguyen, Ph.D., whose telephone number is (571) 272-0776.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's mentor, David Guzo, Ph.D., may be reached at (571) 272-0767, or SPE, Irem Yucel, Ph.D., at (571) 272-0781.

To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Group Art Unit 1636; Central Fax No. (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight

Application/Control Number: 09/721,391

Art Unit: 1636

(EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

Quang Nguyen, Ph.D.

PRIMARY EXAMINER